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Regulations on the Implementation of the Food Safety Law (Revised Draft Notified as SPS 1055)

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Policy and Program Announcements

Approved By:

Jennifer Clever

Prepared By:

FAS Staff

Report Highlights:

On August 14, 2017, China notified the World Trade Organization (WTO) of the "Regulations on the Implementation of the Food Safety Law of the People's Republic of China (Revised Draft)" as SPS 1055. The revised draft regulations are in support of the implementation of China's [2015 Food Safety Law](#). As of this report, the draft implementing regulations do not have a determined date of enforcement. However, it is important to note that some of the listed articles in the revised draft may reflect measures already implemented by different regulatory agencies. The period for submitting comments to the WTO ends on October 13, 2017.

This report provides an unofficial translation of the Revised Draft Implementing Rules and recommendations on how to submit comments.

On August 14, 2017, China notified the World Trade Organization (WTO) of the “Regulations on the Implementation of the Food Safety Law of the People's Republic of China (Revised Draft)” as SPS 1055. The deadline for submitting comments to the WTO is October 13, 2017. This report provides an unofficial translation of the Revised Draft.

How to comment:

At this time, U.S. industry and interested parties are encouraged to offer comments on the Revised Draft as soon as possible. These should be submitted through the USDA/FAS Office of Agreements and Scientific Affairs by email to Joe.Hain@fas.usda.gov.

Individuals/organizations offering comments are also requested to provide copies of their comments to the U.S. Embassy Office of Agricultural Affairs by email to AgBeijing@fas.usda.gov. In order to facilitate comments inclusion regarding this revised draft, please identify the notification number in the email subject line. In addition, kindly reference recommended comments by article before forwarding to FAS.

Background on the Revised Draft

The Revised Draft Implementing Regulations constitutes the third iteration of the Draft Implementing Rules and the only version notified to the World Trade Organization. The China Food and Drug Administration (CFDA) released the [first draft](#) in December 2015. The State Council’s Legislative Affairs Department released the [first revision to the draft](#) later in October 2016. This latest version contains ten chapters and 98 articles, including general principles on risk monitoring and assessment for food safety; food safety standards; the production and marketing of food; food inspection; food import and export; handling of food safety incidents; supervision and management. The Revised Draft also outlines legal responsibilities and provides supplementary provisions. China’s notification to the WTO signals that China is moving closer to finalizing the draft.

In comparison with the first draft of the Implementing Rules released by the China Food and Drug Administration (CFDA) and the first revision, the current draft contains far less articles (first Draft 200 articles, second draft 208 articles, and the current draft 98 articles). Some of the major changes are focused in the sections pertaining to food safety standards, food production and operation, supervision and management, and the legal responsibilities. One of the most significant changes is in the legal responsibilities section. In the event that an entity or a company is found to violate the Food Safety Law, in addition to the punishment imposed on the entity/company, the company personnel are also directly accountable for the violation and therefore also subject to punitive fines.

The Food Safety Law was promulgated two years ago. However, the absence of implementing rules has not allowed some of the requirements provided in the Law to be implemented. Hence, it should be expected that after the Implementing Rules are finalized and released, some existing measures, including major regulations, will need to be revised/developed to reflect changes/new requirements in the Implementing Rules.

BEGIN TRANSLATION

Implementing Rules of the Food Safety Law of the People's Republic of China (Revision Draft)

Chapter I General Provisions

Article 1 These Rules are formulated in accordance with the Food Safety Law of the People's Republic of China (hereinafter referred to as "Food Safety Law").

Article 2 The food producers and operators shall, in accordance with the laws, regulations and food safety standards, engage in production and operation activities, establish and improve food safety management systems, adopt effective management measures, prevent and control risks of food safety risks to ensure food safety.

Article 3 The Food Safety Commission under the State Council is responsible for analyzing food safety situations, studying/deploying and uniformly guiding the national food safety efforts; the Commission proposes major policies and initiatives concerning food safety supervision and management; it urges (relevant government agencies) to fulfill their responsibilities in food safety supervision and management. The Food Safety Commissions under the local people's governments at the county level or above carry out work in accordance with obligations specified by the people's governments at the same level.

The Food Safety Commission Office (FSCO) undertakes daily work of the Food Safety Commission.

Article 4 Local people's governments at the county level or above follow the "chief executive responsibility principle" in food safety supervision and management; they are required to strengthen the capability building for food safety supervision and management, and establish unified and authoritative food safety supervision and management systems.

Food and drug administrative departments and other relevant departments under local people's governments at the county level or above shall perform duties according to law, reinforce coordination, and properly carry out the food safety supervision and management work.

Article 5 The people's governments of township and the sub-district offices shall support the food safety supervision and management work carried out by the county-level food and drug administrative departments and their branches.

Article 6 China will incorporate food safety knowledge into the national quality education programs and the courses taught in primary and secondary schools, strengthen the popularization of scientific and legal knowledge about food safety, and enhance the consciousness of food safety by the whole society.

Article 7 Pursuant to provisions specified by the Ministry of Human Resources and Social Security and the China Food and Drug Administration (CFDA), recognition and rewards shall be given to entities and individuals who make outstanding contributions to food safety efforts.

Chapter II Surveillance and Assessment of Food Safety Risks

Article 8 Health departments under the people's governments of provinces, autonomous regions and municipalities directly under the Central Government ("provincial health departments"), together with food and drug administrative departments and the quality supervision departments of the same level, establish the inter-agency consultation mechanisms for food safety risk surveillance; in which, they will summarize and analyze risk surveillance data, study and determine food safety risks, and prepare analysis reports that are submitted to the provincial people's governments and the National Health and Family Planning Commission (NHFPC).

Article 9 When the food safety risk surveillance result indicates any food safety risks, the food and drug administrative departments and other relevant departments, after further investigation, shall inform relevant food producers and operators in a timely manner when they deem it is necessary to do so.

Upon receiving the notice, the food producers and operators shall immediately take measures to investigate the risks; if any hidden risk of food safety is found, the food producers and operators shall suspend the production, recall the foods, and promptly report it to the food and drug administrative department and relevant departments which have given the notice.

Article 10 If the NHFPC, CFDA and other agencies under the State Council deem it necessary to assess the safety of pesticides, fertilizers, veterinary drugs, feeds and feed additives, they shall propose the risk assessment to the Ministry of Agriculture (MOA). The agricultural department under the State Council shall conduct risk assessment in a timely manner and report the assessment result to the relevant departments under the State Council.

Article 11 The NHFPC shall, as per the need of food safety risk assessment, organize basic research on food consumption, factors that affect food safety, and total diet, etc.

Article 12 CFDA, together with other relevant departments, establish the food safety risk communication mechanism; food producers and operators, technical institutions, testing institutions, certification institutions, food industry associations, consumers' associations, lawyer associations and news media are encouraged and supported to participate in food safety risk communications.

CFDA, together with other relevant departments under the State Council, establish the food safety risk communication advisory commission to provide advice and suggestions for food safety risk communication. The Commission is composed of experts from various fields, including medical science, agriculture, food, nutrition, biology, environment, inspection and quarantine, journalism and communication, and law.

Chapter III Food Safety Standards

Article 13 NHFPC, together with CFDA, the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ), MOA and other relevant departments under the State Council, formulate the national food safety standard plan and the annual implementing plan thereof. The national food safety standard plan and the annual implementing plan thereof shall be released for public comments.

Article 14 Health foods, foods for special medical purposes (FSMP), infant formula foods and new food materials are not foods of local characters, and shall not have local food safety standards.

Article 15 Provincial health departments shall report the local food safety standards to the NHFPC for record-filing within 30 working days upon release of the standards.

Finding local food safety standard that violates laws, regulations or national food safety standards, NHFPC shall promptly make corrections.

Once a national food safety standard is released and comes into force, the corresponding local food safety standard shall be abolished immediately. The provincial health departments shall publish the abolishment of local standards in a timely manner.

Article 16 Enterprise standards developed by food producers shall be available for the public for free. A food producer shall report its enterprise standards to the provincial health departments for record-filing if the standards contain indexes that are stricter than those in the national or local food safety standards. The provincial health departments shall publish the filed standards in their websites.

Chapter IV Food Production and Operation

Article 17 An entity engaging food production, sale and catering services must obtain permits; the permit for food production is valid for five years, and food sale and catering services three years. It is not required to obtain permit for selling edible agricultural products.

Article 18 The food and drug administrative departments at the county level or above shall strengthen the daily supervision and inspection on production and operation activities of food producers and operators; discovering incompliances in food production and operation, they shall order the producer or operator to immediately make corrections and shall impose punishment on the producer or operator according to law; the permit for food production and operation will be revoked when a food producer or operator no longer comply with the permit requirements for food production and operation.

Article 19 NHFPC shall publish the catalogs of new food ingredients, new varieties of food additives and new varieties of food related products, as well as the applicable national food safety standards thereof.

NHFPC, together with CFDA, shall update the catalogs of substances conventionally considered both as food and Chinese medicine in a timely manner.

Article 20 CFDA, together with MOA, shall clarify basic requirements for the food safety traceability of the entire food supply chain; they shall also guide the food producers and operators in establishing and improving the food safety traceability systems.

Article 21 Food producers and operators shall establish their own food safety traceability systems, which enable traceability of foods by faithfully, accurately and completely recording and keeping such data as incoming inspection, pre-delivery inspection and food selling. Foods with high safety risks, foods with large volume of sales, and foods for special consumer groups (such as foods infant formulas) shall be given priority in establishing the food safety traceability systems.

Article 22 The main principal of a food producer or operator shall be accountable for food safety of the enterprise; the person shall establish and implement the food safety responsibility system of the enterprise, putting emphasize on supplier management, incoming inspection, pre-delivery inspection, production and operation control, and food safety self-examination. The food safety management personnel of a food producer or operator shall assist the principal of the enterprise to properly carry out food safety management work.

Article 23 Food producers and operators shall reinforce training and assessment for food safety management personnel. Food safety management personnel shall have knowledge about food safety laws, regulations, rules, standards and the profession that is compatible for their positions; they shall also have the food safety management capability. Food and drug administrative departments shall randomly examine the food safety management personnel of the food producers and operators; the assessment guidance will be developed and published by CFDA.

Article 24 Where a food producer or operator commissions others to produce foods or food additives, the commissioned party shall obtain a food production permit or a food additive production permit. The commissioning party shall be accountable for safety of foods or food additives produced on the commission basis and supervise production by the commissioned party. The commissioned party shall produce foods or food additives in accordance with laws, regulations, food safety standards and the contract.

Article 25 Food producers and operators shall not purchase, use, store or transport non-food use chemical substances that are clearly prohibited from adding into foods and substances that might cause harm to human health.

Article 26 Where the food produced or marketed by a food producer or operator requires irradiation, the food producer or operator shall commission a qualified irradiation service provider to irradiate the food and shall inspect and label the food in accordance with applicable irradiated food standards.

Article 27 Heat preservation, refrigerating or frozen equipment and facilities shall be used for storage or transportation of foods that are subject to special temperature or humidity control requirements; the equipment shall be in effective operation.

Article 28 Where a food producer or operator commissions others to store and transport foods, it shall examine the food safety ensuring capability of the commissioned party, and shall supervise the commissioned party to ensure that foods are stored and transported according to food safety requirements. The commissioned party shall strengthen the processes management to ensure that food storage and transportation conditions meet the food safety requirements.

The entity that is commissioned to store and transport foods shall accurately record food name, specifications, quantity, date of production or batch number, the beginning and ending dates of storage and transportation, as well as the names, addresses, contact information of the consignor and the consignee.

Article 29 A non-food producer or operator that engage in storage or operation of foods, within 30 working days after obtaining business license, report to the local food and drug administrative department at the county level for record-filing.

Article 30 Where a catering service provider commissions a company for centralized tableware cleaning and disinfection shall check and keep copies of the company's business license and disinfection compliance certificates.

Article 31 Schools, kindergartens and nurseries, care centers for the aged, and construction sites with centralized dining facilities shall regularly conduct self-inspections on food safety in the canteens; any risks discovered shall be promptly eliminated.

Whoever contracts and operates the canteen of such entities must obtain relevant catering service license, and shall be accountable for food safety of the canteen. The entities with centralized dining facilities shall urge the contractor to properly implement their food safety management systems.

Article 32 Food producers and operators shall separately store turned, expired or withdraw foods at a clearly marked place, takes harmless treatment or destroy measures, and truthfully record the disposal measures.

Article 33 People's governments at the county level or above shall build facilities for harmless treatment or destroying foods based on needs. Food producers and operators could use the facilities built by governments to take harmless treatment or destroying measures to dispose foods according to relevant provisions.

Article 34 Food and drug administrative departments under the people's governments at the county level shall specify food safety management requirements for group dining, provide guidance for catering service providers and tableware and drinking utensil providers.

Article 35 Before opening a market or holding a trade fair related to food operation, the owner or organizer of the market/fair shall file record with the local food and drug administrative department at the county level.

Article 36 An online food trading third-party platform provider shall properly keep the registration data and trading data. When a food and drug administrative department needs to know relevant data during food safety supervision and inspection, case investigation and handling or incident handling, the online food trading third-party platform provider shall provide the said data according to relevant requirements. The food and drug administrative department shall keep the data provided by the online food trading third-party platform provider secret.

Article 37 For substances that shall not be used according to food safety standards, a food producer or operator shall not claim that the said substance are not added on the food labels, in the instructions or in the advertisements.

For any food other than health foods, health function shall not be claimed.

Article 38 False advertising by any means including conference, lecture, health consultation is forbidden. Food and drug administrative departments shall strengthen supervision and inspection of false advertising by conference, lecture, health consultation or by other means, and deal with any false advertising if found.

Article 39 Where during production procedure of health food there are such pre-treatment processes as extraction of ingredients and purification, the producer must have corresponding capability of ingredient pre-treatment and conduct pre-treatment by itself.

Article 40 When developing specific administration measures according to provisions of Article 152 of the Food Safety Law, CFDA shall widely consult health food producers and operators, industrial associations and consumers.

Article 41 A producer of FSMP shall inspect each batch of factory products to be dispatched from the factory according to testing items required by the applicable national food safety standards.

The special whole-nutrient formula foods under the FSMP category shall be sold in hospitals or medicine retailers, but not on Internet. Medical institutions and medicine retailers which sell special whole-nutrient formula foods don't need to obtain food selling license but shall comply with the Food Safety Law and provisions related to food selling in these Rules.

Article 42 Advertisements for the specific whole-nutrient formula food under the FSMP category shall be regulated as those for prescribed medicines; advertisements of other FSMP shall be regulated as non-prescribed medicines.

Article 43 The labels of infant formula foods shall truthfully indicate the specific sources of materials.

Infant formula foods adding optional substances permitted by national food safety standards shall not be named using the optional substance.

Infant formula foods shall not have function claims.

Article 44 The content of labels and instructions of health foods, FSMP and infant formula foods shall be consistent with that of the labels and instructions used in registration and record filing. CFDA shall publish on its website labels and instructions of the health foods, FSMP and infant formula foods that are registered or filed records with the CFDA.

Operators, while selling health foods, FSMP and infant formulas, must examine whether the content of the labels and instructions of the sold products are consistent with the labels and instructions used in registration and record filing; it is not allowed to sell products with labels or instructions that are inconsistent with those registered or filed for records.

Health foods, FSMP and infant formula foods shall not be commingled for sale with regular foods or drugs.

Chapter V Food Test

Article 45 The food and drug administrative departments shall commission qualified institutions to carry out sampling test for foods. The sampling tests for foods shall be conducted in accordance with the applicable food safety standards, specifications for foods that have registered or filed for records, and the testing items and methods specified in relevant regulations.

Article 46 Applying for a re-test according to Article 88 of the Food Safety Law, the re-test cost shall be paid by the re-test applicant before the test. If the re-test conclusion is the same as that of the initial test, the re-test cost is borne by the re-test applicant; if the re-test conclusion is different from the initial test, the re-test cost is borne by the food and drug administrative department that initially tested the product.

Article 47 Re-test institutions shall not reject carrying out re-test tasks. Refusing to take re-test tasks for two times in a year, the re-test institution's qualification for re-test will be cancelled by the relevant departments under the State Council, and issue public notices about the cancellation.

Article 48 Any entity or individual shall not publish any food inspection data issued by any food inspection institution which has not obtained qualification according to law, and shall not use the said inspection data for rating for food or food producers or operators to deceive or mislead consumers.

Chapter VI Food Import and Export

Article 49 When importing foods and food additives, the importers shall make declarations to the entry-exit inspection and quarantine authorities (CIQs) for inspection, submit product-related information and compliance materials along with the declaration; when importing health foods, FSMP or infant formula

powder products that are subject to registration requirements, the importers shall also provide the registration certificates issued by the CFDA.

Article 50 Imported foods shall be stored at the sites designated or recognized by CIQs upon arriving at ports. Imported bulk commodities shall be inspected at the port, and shall not be moved without inspection; other foods necessary for moving could only be moved after getting CIQ approval and taking necessary quarantine or safety protection measures.

Article 51 According to the principles of risk management, AQSIQ may confirm, release and implement the list of foods that shall be imported through designated ports.

Article 52 Foods without national food safety standards mentioned in Article 93 of the Food Safety Law refers to the foods produced by foreign food producers that do not have eligible national food safety standards in China; it does not include foods that are already covered by the general or fundamental standards of the published national food safety standards.

NHFPC conducts examinations on relevant standards according to Article 93 of the Food Safety Law; deeming the standard consistent with the food safety requirements, NHFPC will temporarily adopt the standard and make announcement accordingly; before announcing the temporarily applicable standard, it is not allowed to import foods without national food safety standards.

Article 53 An importer shall establish a system to review foreign food exporters/foreign food producers, which shall focus on reviewing the following items:

- (i) Whether the food exported to China from foreign food exporters/foreign food producers complies with Food Safety Law, relevant regulations and national food safety standards;
- (ii) How foreign food exporters/foreign food producers develop and implement food safety risk control measures to ensure that food exported to China complies with the Food Safety Law, relevant regulations and national food safety standards.

Article 54 Recalling imported food in accordance with the Article 94.3 of the Food Safety Law, the importer shall also report the food recall and treatment to the local CIQ.

Article 55 Noticing a registered foreign food producer that no longer complies with the registration requirements, AQSIQ shall order the producer to make rectification within given time; while the producer is taking the rectification measures, imports of foods produced by the company shall be suspended; where the producer still fail to comply with the registration requirements after taking the rectification measures, AQSIQ shall revoke the foreign food producer's registration, and make an announcement.

Article 56 For foreign food producers that have passed the good manufacturing practices (GMP) and the hazard analysis and critical control point (HACCP) assessments in China, the certification authority

shall conduct follow-up inspections according to law. The certification agency shall revoke the certification issued to the producers that no longer meet the certification requirements and make public announcement.

Article 57 In the event that a food safety incident occurring abroad may impact China or noticing serious food safety problems in imported foods, food additives or food related products, AQSIQ shall promptly issue a risk alert for the imported food, and may take the following control measures:

- (i) Reject or destroy the food;
- (ii) Restrict import of the food with conditions;
- (iii) Suspend or prohibit import of the food.

Article 58 Producers of foods and food additives for export shall ensure that their foods and food additives for export comply with standards of the importing county (region) or the contract requirements. Where the international treaty or protocol China concluded or participated sets requirements, foods and food additive exports shall also meet requirements set in the international treaty or protocol.

Chapter VII Handling of Food Safety Incidents

Article 59 Food safety incidents, pursuant to the National Food Safety Incident Responding Plans, shall be administered in several levels. The food and drug administrative departments under the at the county level or above, together with relevant departments at the same level, are responsible for investigation and handling of food safety incidents.

The people's governments at the county level or above shall modify and improve the food safety incident responding plans based on the actual situation in a timely manner.

Article 60 The people's governments at the county level or above shall improve the food safety incident responding mechanisms, guarantee availability of funds for the incident response, improve the equipment, store the emergency response materials, and build the emergency response team; they shall also strengthen emergency response trainings and drills.

Food producers shall regularly conduct food safety incident responding drills.

Article 61 An entity that have a food safety incident shall immediately take control measures, such as sealing up the foods and ingredients, tools and equipment that caused or may have caused food safety incidents. The entity that have the incident and the entity that receives patients from the incident shall notify the local food and drug administrative department and the health department within the time limit provided in the incident responding plan. Receiving the notification, the food and drug administrative department at the county level shall report the incident to the food and drug administrative department of

the higher level in accordance with the provisions in the incident responding plan. The food and drug administrative department at the county level or above shall conduct investigation into the incident and take actions in accordance with provisions in Article 105 of Food Safety Law.

Article 62 Noticing the received patients are infected with foodborne disease or are suspected of such illness, the medical institution shall promptly notify the local health department at the county level according to relevant provisions. Deeming the illness is relevant to food safety incidents, the health department at the county level shall report the cases to the food and drug administrative department at the same level within two hours.

Discovering information relating to food safety incidents in investigating and handling contagious diseases or other public health incident outbreak, the health department at the county level or above shall report such incidents to the food and drug administrative department at the same level within two hours.

Receiving such report from the health department, the food and drug administrative department shall conduct investigation within two hours; finding the incident a food safety incident, the food and drug administrative department shall conduct investigation into the incident and take actions in accordance with provisions in Article 105 of Food Safety Law..

Article 63 While investigating and handling food safety incidents and needing to conduct epidemiological investigation into factors related to the incidents, the food and drug administrative department at the county level or above shall notify the disease prevention institution, and assist the disease prevention institutions in the investigation work. Any entity or individual shall not reject or hinder the epidemiological investigation conducted by the disease prevention institution. The disease prevention institution shall submit epidemiological investigation reports to the food and drug administrative department and the health department at the same level in a timely manner.

Article 64 CFDA, NHFPC, AQSIQ and MOA shall analyze the food safety incidents situations nationwide on a regular basis; they shall improve the food safety supervision and management measures to prevent and reduce occurrence of incidents.

Chapter VIII Supervision and Management

Article 65 China establishes the food safety inspector system and will set up the full-time food safety inspector teams.

Article 66 Where a food producer or operator is being investigated by a food and drug administrative department due to any alleged illegal activity concerning food safety, the food and drug administrative department may suspend accepting the company's relevant application for administrative license during the course of case investigation and handling; where the application has been accepted, the processing shall be suspended, and the suspension period shall not be counted in the time limit of processing the application for administrative license.

Article 67 CFDA shall, together with relevant departments under the State Council, and based on the information of foodborne illness, information of risk surveillance, assessment, supervision and management. NHFPC is responsible for developing and publishing the testing methods for the said substances.

Article 68 CFDA may, as per the needs of supervision and management of food safety, assess the rapid food test methods; if the assessment result meets the relevant requirements, such methods may be used for sampling test for foods.

In accordance with the national food recall regulations, food producers or traders shall terminate production/trading of unsafety foods, recall and dispose the unsafety foods.

Based on seriousness and emergency grade of food safety risks, food recalls could be categorized to the following grades:

Article 69 Where an online food trading third-party platform has multiple cases caused by the illegal operation of the on-line food operators that cause serious consequences, the food and drug administrative department at the county level or above may invite the legal representative or principal of the online food trading third-party platform providers to a meeting about their accountability.

Article 70 The municipal governments of the municipalities with districts and the food and drug administrative departments at the county level, in addition to works listed in the annual supervision and management plans, may conduct off-site supervision and inspection according to arrangement by the food and drug administrative departments under the provincial governments.

Article 71 Upon occurrence of any of the following circumstances, the provincial food and drug administrative department may conduct supervision and inspection on food producers and operators which are under supervision and inspection by the administrative department at the lower level:

- (i) A food producer or operator is suspected of violating food safety laws or regulations, which may cause serious harm;
- (ii) A food producer or operator has hidden peril of food safety, which may cause regional or systematic food safety risk, or would cause serious harm;
- (iii) Other circumstances deemed necessary by CFDA.

Article 72 When it is considered necessary, the food and drug administrative department at the higher level may directly investigate food safety violation case that are subject to jurisdiction of the lower level food and drug administrative department; the food and drug administrative department of the place where the case occurs shall offer coordination.

Article 73 The health departments at the county level or above shall conduct supervision and inspection on companies for centralized tableware cleaning and disinfection; finding any incompliance with laws, regulations, food safety standards or relevant health requirement, the health department shall conduct investigation and take actions in a timely manner.

Results of the supervision and inspection shall be released to the public.

Article 74 CFDA shall, together with the NHFPC, AQSIQ, and MOA, develop and publish the annual national food safety situation report.

Article 75 While handling criminal cases involving food safety, when there is a need to control the food safety risks, the public security bureau shall notify the food and drug administrative department and the quality supervision departments at the same level to take measures to control the food safety risks.

Article 76 Where a food producer or operator is suspected of a crime of endangering food safety, during the case filing and investigation, review, prosecution and trial, the food and drug administrative department and any other relevant departments may take necessary control measures.

Chapter IX Legal Liabilities

Article 77 Where an entity has any of the circumstances specified in Article 122.1 of the Food Safety Law, in addition to the penalty imposed by the Article 122.1 of the Food Safety Law, the principal staff, the managers directly responsible and other persons directly responsible for the violation shall be imposed a penalty of more than one time and less than five times of their annual salaries of the previous year.

Article 78 Where there is any of the circumstances specified in Article 123.1 of the Food Safety Law which does not constitute a crime, but is considered as a “serious circumstance” of the Article 123.1 of the Food Safety Law:

- (i) The value of the illegally produced and traded foods is more than 30,000 yuan;
- (ii) It causes food poisoning or other foodborne illness to more than 5 people.

Article 79 Where an entity has any of the circumstances specified in Article 123.1 of the Food Safety Law, in addition to the penalty imposed by the Article 123.1 of the Food Safety Law, the principal staff, the managers directly responsible, the food safety manager and other persons directly responsible for the violation shall be imposed a penalty of more than one time and less than five times of their annual salaries of the previous year.

Article 80 Where there is any of the circumstances specified in Article 124 and Article 129.1 of the Food Safety Law which does not constitute a crime, but is considered as a “serious circumstance” of the Article 124.1 of the Food Safety Law:

- (i) The value of the illegally produced/traded foods or food additives exceeds 50,000 yuan; the value of the produced or traded health foods, FSMP, or infant formula powder that do not have required registration exceeds 30, 000 yuan;
- (ii) The value of illegally imported or exported food, food additives or food related products exceed 50, 000 yuan;
- (iii) Producing or operating foods or food additives that contain pollutants (such as pathogenic microorganism, pesticide residue, veterinary drug residue, biotoxin and heavy metals) or other harmful substances at the level severely exceed limits provided in the food safety standards;
- (iv) It causes food poisoning or other foodborne illness to more than 10 people.

Where a producer does not produce health foods, FSMP or infant formula powder according to the registered recipe or the registered technical requirements, and the violation is serious, CFDA will revoke the registration certificate. The producer whose registration certificate is revoked cannot apply for registration of health foods, FSMP or infant formula powder recipe in five years after the decision for punishment is made.

Article 81 Where there is any of the circumstances specified in Article 124 and Article 129.1 of the Food Safety Law, in addition to the penalty imposed by the Article 124 and Article 129.1 of the Food Safety Law, the principal staff, the managers directly responsible, the food safety manager and other persons directly responsible for the violation shall be imposed a penalty of more than 30% and less than one time of their annual salaries of the previous year.

Article 82 Where there is any of the circumstances specified in Article 125.1 of the Food Safety Law, i.e. value of the illegally produced/traded foods or food additives exceed 100,000 Yuan, the violation is considered as a “serious circumstance” of the Article 125.1 of the Food Safety Law:

Article 83 Where there is any of the circumstances specified in Article 125.1 of the Food Safety Law, in addition to the penalty imposed by the Article 125 of the Food Safety Law, the principal staff, the managers directly responsible, the food safety manager and other persons directly responsible for the violation shall be imposed a penalty of more than 20% and less than 50% of their annual salaries of the previous year.

Article 84 Where there is any of the following circumstances as provided in Article 126 and Article 129.2 of the Food Safety Law, and the said circumstance occurs again six months after the entity receives a warning or being fined, or the punished person/entity makes no correction after getting fined, it is deemed as a "serious circumstance" as specified in Article 126.1 of the Food Safety Law.

Article 85 Where an entity has any of the circumstances specified in Article 126 and Article 129.2 of the Food Safety Law and the circumstance is serious, in addition to the penalty imposed to the entity according to Article 126 and Article 129.2 of the Food Safety Law, the principal staff, the managers

directly responsible, the food safety manager and other persons directly responsible for the violation shall be imposed a penalty of more than 2,000 Yuan and less than 20,000 Yuan.

Article 86 Where an entity has any of the circumstance specified in Article 128 of the Food Safety Law, and conceals, forges or destroys relevant evidences or causes serious consequences, in addition to the penalty imposed to the entity according to Article 128 of the Food Safety Law, the principal staff, the managers directly responsible, the food safety manager and other persons directly responsible for the violation shall be imposed a penalty of more than 20,000 Yuan and less than 100,000 Yuan

Article 87 Where an entity has any of the circumstance specified in Article 130 and Article 131.1 of the Food Safety Law which causes serious consequences, in addition to the penalty imposed to the entity according to Article 130 and Article 131.1 of the Food Safety Law, the principal staff, the managers directly responsible and other persons directly responsible for the violation shall be imposed a penalty of more than 20,000 Yuan and less than 50,000 Yuan

Article 88 Where an entity has any of the circumstance specified in Article 132 and Article 140.5 of the Food Safety Law, the entity refuses to make corrections or has a serious circumstance, in addition to the penalty imposed to the entity according to Article 132 and Article 140.5 of the Food Safety Law, the principal staff, the managers directly responsible, the food safety manager and other persons directly responsible for the violation shall be imposed a penalty of more than 2,000 Yuan and less than 10,000 Yuan

Article 89 In addition to the circumstances specified in Article 126 of the Food Safety Law, where the food producer or operator's production or operation does not comply with provisions of Item 5 to 10 of the Article 33.1 of the Food Safety Law, does not comply with provisions of the national food safety standards related to sanitary requirement on food production process, a penalty will be imposed according to Article 126.1 of the Food Safety Law and Article 85 of these Rules.

Article 90 Violation of Article 75.3 of the Food Safety Law by using materials other than those in the health food material list are used to produce food other than health food, penalty is imposed according to Article 124.1 of the Food Safety Law and Article 81 of these Rules:

Article 91 Violating these Rules with any of the following circumstances, a penalty will be imposed according to Article 125.1 of the Food Safety Law and Article 83 of these Rules:

- (i) In food production and operation, the entity/person purchases, uses, stores, or transports the non-food use chemical substances banned to be added into foods or substances that may cause harm to human health;
- (ii) Label or the instructions of the produced or operated foods claims not adding substances that shall not be used in accordance with the food safety standards;

- (iii) Label or the instructions of the produced or operated foods that are not health foods claims for health functions;
- (iv) False promotion of foods in forms of holding conferences, lectures, or health consultations;
- (v) Labels and instructions of infant formula foods do not specify sources of the materials as requested;
- (vi) Name infant formula foods after substances that are allowed to be optionally added by relevant national food safety standards;
- (vii) Labels and instructions of infant formula foods contain function claims;
- (viii) The content of the labels and instructions of the health foods, FSMP and infant formula foods is not consistent with that in the labels and instructions registered and filed on the record.

Article 92 Violating these Rules with any of the following circumstances, a penalty will be imposed according to Article 126 of the Food Safety Law and Article 85 of these Rules:

- (i) An entity that is commissioned to store and transport foods does not record information as required;
- (ii) A catering service provider does not check business license and disinfection compliance certificate of the centralized tableware and drinking utensil providers and keep a copy of the certificates;
- (iii) A food producer or operator does not store spoiled, expired or recycled foods at a separate location with clear signs, or does not take disposal measures (such as harmless treatment or destroying) the aforementioned foods and take truthful records;
- (iv) An entity or an individual other than medical institutions and medicine retailers sells special whole-nutrient formula foods under the FSMP category, or sell the special whole-nutrient formula foods via the Internet;
- (v) Store or sell health foods, FSMP and infant formula foods together with regular foods or drugs.

Article 93 Violations to these rules, such as a non-food producer or operator engaging in food production or operation, or an operator of the centralized food trading market or an organizer of a trade fair does not file for record (to relevant authorities) will be instructed by the food and drug administrative department at the county level or above to make rectifications and get warnings; where the entity/person refuses to make rectification, a fine of more than 5,000 Yuan but less than 50,000 Yuan will be imposed; where the circumstance is serious, the entity will be instructed to terminate production or business operation.

Article 94 Finding an entity/individual violating these rules by publishing food inspection data issued by an unqualified food inspection institution or using the above inspection data for rating foods or food producers/operators to mislead consumers, the food and drug administrative department at the county level or above will instruct the entity/individual to take rectification measures; the food and drug administrative department will confiscate the entity/individual's illegal gains if there any. Where the entity/individual refuses to make rectification, the food and drug administrative department will impose a fine of more than 50,000 Yuan but less than 200,000 Yuan; where there is a serious circumstance, the department orders the entity or individual to stop production and business operation; if the entity/individual violates public security regulations, the relevant public security punishment shall be carried out by the public security authorities.

Article 95 In the circumstance that a food and drug administrative department at the county level fail to clarify food safety requirements for group dining, or fail to perform their guiding duty in group dining, which causes a food safety incident is caused, the responsible directors and other directly responsible personnel will be punished in accordance with Article 144 of the Food Safety Law; where it causes serious consequences, the principal staff of the department shall take the blame and resign.

Article 96 Where any food and drug administrative department violates these Rules and provides other people with the data provided by online food trading third-party platform providers, the responsible directors and other directly responsible personnel will be punished in accordance with Article 145 of the Food Safety Law.

Chapter X Supplementary Provisions

Article 97 Applicants who apply for registration of the health foods, FSMP and recipes of infant formula powder shall pay the registration fee. The registration fee rates shall be determined by the competent price authority under the State Council together with the Ministry of Finance and CFDA.

Article 98 These Rules enter into force as of _____ (date).

END OF TRANSLATION